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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,131	02/16/2001	Adrian Gilbert	60623-A/JPW/GJG/CSN	5640

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/788,131	GILBERT ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-35,37-43,50-55 and 61-74* is/are pending in the application.

4a) Of the above claim(s) *55 and 67-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-35,37-43,50-54 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of Provisional Application No. 60/183,666, filed February 18, 2000.

Claims 2, 36, 44-49 and 56-60 have been canceled.

Claims 1, 3-35, 37-43, 50-55 and 61-74 are currently pending.

Election/Restrictions

Claims **55 and 67-74 stand withdrawn**.

Claims 1, 3-35, 37-43, 50-54 and 61-66 are the subject of examination in the present Office Action.

In view of Applicant's remarks filed September 27, 2004, no outstanding ground of rejection is maintained. The following grounds of rejection represent NEW grounds of rejection and this Office Action is accordingly made NON-FINAL.

Applicant's arguments with respect to claim 1, 3-35, 37-43, 50-54 and 61-66 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3-35, 37-43, 50-54 and 62, 63 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003; of record) in view of U.S. Patent No. 5,075,115 to Brine (A2 on form PTO-892; newly cited).

Specifically, claims 7-11 of the '791 patent are drawn to the use of copolymer-1 for the manufacture of a medicament or pharmaceutical composition for the treatment of multiple sclerosis via ingestion or inhalation (7), wherein the medicament comprises 0.1-1000 mg of copolymer-1 (8), is formulated for oral or nasal administration (9), is administered via inhalation (10), or is enterically coated (11). Claim 7 of the '791 patent is a genus claim which broadly encompasses the presently claimed method of making a copolymer-1 medicament in light of the disclosure of the '981 patent [Instant claims 43 and 64-65]. Claims 12-14 are drawn to a pharmaceutical composition for the treatment of multiple sclerosis via ingestion or inhalation (12), wherein the pharmaceutical composition is in solid, liquid, aerosol or inhalable powder form (13), or is enterically coated (14). Claim 12 of the '791 patent is a genus claim which broadly encompasses the presently claimed pharmaceutical composition in light of the further disclosure of the '791 patent and the disclosure of the '981 patent.

The pharmaceutical composition recited in claim 12 of the '791 patent comprises as an active ingredient a therapeutically effective amount of Copolymer 1(glatimer acetate). As is evidenced by the disclosure of the '791 patent, the composition is used to treat multiple sclerosis by oral administration of copolymer-1 through ingestion, and that when copolymer-1 is introduced orally it may be in solid form, and it may be mixed with pharmaceutically acceptable carrier. The disclosure of the '791 patent indicates that the use of enteric coatings is well known in the art, including methacrylic acid copolymer (Eudragit L; column 3, lines 27-42 in particular)[Instant claims 18, 20, 29-31]. The '791 patent further discloses that the administration of the composition orally, nasally or bronchially in liquid or solid form with a range of copolymer-1 from 0.1 to 1000 mg (column 2, line 45 to column 3, line 26) [claims 23-28, 32-42, 50-54, 62-63].

The '791 patent does not specifically recite that said carrier is microcrystalline cellulose in an amount in excess of 50% by weight or admixture with a lubricant.

Microcrystalline cellulose is well known in the art as a stable and physiologically inert excipient.

The '115 patent teaches the formulation of pharmaceutical compositions as a controlled release dosage form. The '115 patent teaches that the formulation of the invention may employ "[a]ny pharmaceutically active ingredient (column 3, lines 61-63 in particular). The '115 patent further teaches that an excipient may be employed in the formulation as a diluent, a binder, a lubricant, a disintegrant, an adsorbent or a combination of functions. The '115 patent further teaches that excipients are selected by the artisan "to provide their usual contribution" and "may be employed in an amount varying from 1% to about 90% by weight of the dosage form" (column 5, lines 10-21 in particular). The '115 patent teaches that microcrystalline cellulose is "particularly desirable" as an excipient and is suitable as a binder,

diluent and as a disintegrant. The '115 patent teaches that microcrystalline cellulose is porous and can absorb a liquid medicament while remaining a free-flowing powder suitable as a feed formulation for compression. The '115 patent teaches in Examples 1 and 2 that release of active ingredient was more efficient when the percent-by-weight of the active ingredient was 25% and microcrystalline cellulose was 60% (Table III in particular) than when the percent-by-weight of the active ingredient was 60% and microcrystalline cellulose was 25% (Table II in particular). The '115 patent further teaches the use of magnesium stearate as a lubricant in the feed formulation (column 6, lines 17-37n particular)[claims 15-17].

Claims 34-35 are included because the use of preservatives in pharmaceutical formulations is well known to enhance the longevity of the formulation in storage.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to manufacture a composition comprising copolymer-1 as recited in claims 7-14 of the '791 patent using microcrystalline cellulose as an excipient and magnesium stearate as a lubricant as taught by the '115 patent. One would have been motivated to combine these teachings using in excess of 50% microcrystalline cellulose with a reasonable expectation of success by the teachings of the '115 patent that microcrystalline cellulose can be used with any pharmaceutically active ingredient, is multi-functional as an excipient, has preferable properties for serving as a feed formulation in the manufacture process, and the showing that 60% microcrystalline cellulose by weight in the pharmaceutical composition yields more efficient release of the pharmaceutically active ingredient than 25% microcrystalline cellulose by weight.

2. Claims 1, 20, 21, 22, 43 and 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003; of record) in view of U.S. Patent No. 5,075,115 to Brine (A2 on form PTO-892; newly cited) and U.S. Patent No. 5,965,600 to Sato et al (B on form PTO-892; of record).

The '791 and '115 patents have been discussed supra.

The combined disclosures do not specifically recite film coating of the solid form in combination with the enteric coating.

The '600 patent teaches a medicament in tablet form comprising both an enteric coating and a film coating, which could be polyvinyl alcohol (column 4, lines 39-62 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '600 patent with the combined disclosures of the '791 and '115 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '600 patent that multiple coatings of a tablet including both enteric and film coatings is "customary" in the art.

3. Claims 1 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003; of record) in view of U.S. Patent No. 5,075,115 to Brine (A2 on form PTO-892; newly cited) and U.S. Patent No. 6,162,800 to Dolle et al (C on form PTO-892; of record).

The '791 and '115 patents have been discussed supra.

The combined disclosures do not specifically recite protease inhibitors in a medicament for multiple sclerosis.

The '800 patent teaches a pharmaceutical composition comprising a protease inhibitor for the treatment of IL-1β mediated disease states (column 7, lines 39-56 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '800 patent with the combined disclosures of the '791 and '115 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '800 patent that multiple sclerosis is an IL-1β mediated disease state which can be treated with medicaments comprising a protease inhibitor.

4. Claims 43, 65 and 66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-11 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003; of record) in view of U.S. Patent No. 5,075,115 to Brine (A2 on form PTO-892; newly cited) and U.S. Patent No. 4,129,666 to Wiżerkaniuk (D on form PTO-892; of record).

The '791 and '115 patents have been discussed supra.

The combined disclosures do not specifically recite the use of a rotating pan for application of the enteric coating to the solid form of the pharmaceutical composition.

The '666 patent teaches the application of enteric coating medicinal pellets with an enteric coating using a rotating pan apparatus (entire patent).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '666 patent with the combined disclosures of the '791 and '981 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '666 patent that methods of applying an enteric coating such as spraying requires the use of solvents which may be toxic, while the rotating pan method does not require such solvents (column 1, lines 24-56 in particular).

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
November 8, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
11/10/04